

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6815.US.01	Serial No.: 10/623,194
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date: 10/09/01	Group: 1615

**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
IG	6,221,910	04/24/01	Montner			
	5,462,924	10/31/95	Kihlberg, et al.			
	5,646,118	07/08/97	Kihlberg, et al.			
	5,908,824	06/01/99	Yanagawa			
IG	5,693,671	12/02/97	Niihara, et al.			

**FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)
IG	EP 1 097 646 A2	05/09/01				
IG	EP 0 547 099 B1	07/30/97				
IG	WO 92/03155	03/05/92				
	JP 10-101576	no date				

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

IG		Bruto, et al., "Stable Glutamine Derivatives Reduce Apoptosis in Intestinal Epithelial Cells and Inhibit Cholera Toxin Secretion", American Journal of Tropical Medicine and Hygiene, V. 62 (3 Suppl), 367-368, no. 547
IG		Patents Abstract of Japan, application number 08260683
IG		Alitraq® Specialized Elemental Nutrition with Glutamine for Metabolically Stressed Patients with Impaired GI Function, Ross Products Division of Abbott Laboratories
IG		Optimental® Ready To Feed Elemental, Ross Products Division of Abbott Laboratories
IG		Sigma-Aldrich Certificate of Analysis, N-Acetyl -L-glutamine, Product Number A9125
EXAMINER /Isis Ghali/		DATE CONSIDERED: 08/03/2006

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FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6815.US.01	Serial No.: 10/623/94
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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

IG		Rothstein, et al., "Chronic Inhibition of Glutamate Uptake Produces a Model of Slow Neurotoxicity", Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 6591-6595, July 1993, Neurobiology
IG		Caccia, et al., "Pyroglutamate Kinetics and Neurotoxicity Studies in Mice", Toxicology Letters, 16 (1983) 225-229
IG		McGeer, et al., "Research Note: Neurotoxic Effects of Endogenous Materials: Quinolinic Acid, L-Pyroglutamic Acid, and Thyroid Releasing Hormone (TRH)", Experimental Neurology 86, 410-413 (1984)
IG		Creer, et al., "Pyroglutamic Acidemia in an Adult Patient", Clinical Chemistry, Vol. 35, No. 4, 1989
IG		Magnusson, et al., "Utilization of Intravenously Administered N-Acetyl-L-Glutamine in Humans", Metabolism, Vol. 38, No. 8, Suppl 1 (August), 1989: pp. 82-88
IG		Gouttebel, et al., "Influence of N-Acetylglutamine or Glutamine Infusion on Plasma Amino Acid Concentrations During the Early Phase of Small-Bowel Adaptation in the Dog", Journal of Parenteral and Enteral Nutrition, Vol. 16, No. 2, 1992
IG		Ollenschläger, et al., "Availability of Glutamine From Peptides and Acetylglutamine for Human Tumor-Cell Cultures", Metabolism, Vol. 38, No. 8, Suppl 1 (August) 1989: pp. 40-42
IG		Palmerini, et al., "Uptake of Doubly-Labelled N-Acetyl-L-Glutamine in Rat Brain and Intestinal Mucosa <i>In Vivo</i> ", Farmaco[Prat], 1981 July, 36(7): 347-55
IG		Wallace, et al., "Uptake of Acetylated Peptides from the Small Intestine in Sheep and Their Nutritive Value in Rats", British Journal of Nutrition (1998), 80, 101-108
IG		Damico, "An Investigation of N-Substituted Methionine Derivatives for Food Supplementation", J. Agr. Food Chem., Vol. 23, No.1, 1975
IG		Rotruck, et al., "Comparative Metabolism of L-Methionine and N-Acetylated Derivatives of Methionine", The Journal of Nutrition, Vol. 105, No. 3, March 1975
IG		Boggs, et al., "Acetylmethionine as a Source of Methionine for the Rat", The Journal of Nutrition, Vol. 105, No. 3, March 1975
IG		Tanabe, et al., "Production of a High-Glutamine Oligopeptide Fraction from Gluten by Enzymatic Treatment and Evaluation of its Nutritional Effect on the Small Intestine of Rats", Journal of Biochemistry 16, (1993), 235-248
IG		Rooyackers, et al., "Effect on Enterally Administered Glutamine-Rich Protein on the Catabolic Response to a Zymosan Challenge in Rats", Clinical Nutrition (1995) 14: 105-115
IG		Jiang, et al., "The Impact of Alanyl-Glutamine on Clinical Safety, Nitrogen Balance, Intestinal Permeability, and Clinical Outcome in Postoperative Patients: A Randomized, Double-Blind, Controlled Study of 120 Patients", Journal of Parenteral and Enteral Nutrition, Vol. 23, No. 5, 1999
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

IG		van Zaanen, et al., "Parenteral Glutamine Dipeptide Supplementation Does Not Ameliorate Chemotherapy-Induced Toxicity", <i>CANCER</i> , November 15, 1994, Vol. 74, No. 10
		Scheppach, et al., "Effect of Free Glutamine and Alanyl-Glutamine Dipeptide on Mucosal Proliferation of the Human Ileum and Colon", <i>Gastroenterology</i> , 1994; 107: 429-434
		Klassen, et al., "The Pharmacokinetic Responses of Humans to 20 g of Alanyl-Glutamine Dipeptide Differ with the Dosing Protocol but Not with Gastric Acidity or in Patients with Acute Dengue Fever", <i>J. Nutr.</i> 130: 177-182, 2000
		Tenerhaus, et al., "Supplementation of an Elemental Enteral Diet with Alanyl-Glutamine Decreases Bacterial Translocation in Burned Mice", <i>Burns</i> (1994) 20, (3), 220-225
		van der Hulst, et al., "Glutamine and the Preservation of Gut Integrity", <i>The Lancet</i> , Vol. 341: May 29, 1993
		Wirén, et al., "The Effects of a New Amino-Acid Dipeptide Solution on Nitrogen Balance and Humoral Growth Factors in the Postoperative State in Man", <i>Clinical Nutrition</i> , (1995) 14: 97-104
		Decker-Baumann, et al., "Reduction of Chemotherapy-induced Side-effects by Parenteral Glutamine Supplementation in Patients with Metastatic Colorectal Cancer", <i>Eur J Cancer</i> , Vol. 35, No. 2, pp. 202-207, 1999
		Tremel, et al., "Glutamine Dipeptide - Supplemented Parenteral Nutrition Maintains Intestinal Function in the Critically Ill", <i>Gastroenterology</i> , 1994; 107: 1595-1601
		Ziegler, et al., "Safety and Metabolic Effects of L-Glutamine Administration in Humans", <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 14, No. 4, Supplement, 1990
		Hankard, et al., "Response of Glutamine Metabolism to Exogenous Glutamine in Humans", <i>Am J Physiol</i> 1995 Oct; 269 (4 Pt 1): E663-70
		Anderson, et al., "Oral Glutamine Reduces the Duration and Severity of Stomatitis after Cytotoxic Cancer Chemotherapy", <i>CANCER</i> , October 1, 1998, Vol. 83, No. 7
		Abcouwer, et al., "Is Glutamine a Pretender to the Throne?", <i>Nutrition</i> , Vol. 15, No. 1, 1999
		Saito, et al., "Glutamine as an Immunoenhancing Nutrient", <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 23, No.5, 1999
		Wells, et al., "Dietary Glutamine Enhances Cytokine Production by Murine Macrophages", <i>Nutrition</i> , Vol. 15, Nos. 11/12, 1999
		Jones, et al., "Randomized Clinical Outcome Study of Critically Ill Patients Given Glutamine-Supplemented Enteral Nutrition", <i>Nutrition</i> , Vol. 15, No. 2, 1999
		Barbosa, et al., "Pilot Study with a Glutamine-Supplemented Enteral Formula in Critically Ill Infants", <i>Rev. Hosp. Clin. Fac. Med. S.Paulo</i> , 54(1): 21-24, 1999
		Houdijk, et al., "Randomised Trial of Glutamine-Enriched Enteral Nutrition on Infectious Morbidity in Patients with Multiple Trauma", <i>The Lancet</i> , Vol. 352, September 5, 1998
IG		Long, et al., "Impact of Enteral Feeding of a Glutamine-Supplemented Formula on the Hypoaminoacidemic Response in Trauma Patients", <i>The Journal of Trauma: Injury, Infection, and Critical Care</i> , Vol. 40, No. 1, 1996
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## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
IG	5,561,111	10/01/96	Guerrant, et al.			
	5,039,704	08/13/91	Smith, et al.			
	4,857,555	08/15/89	Smith, et al.			
IG	5,248,697	09/28/93	Wilmore			

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

IG		Rouse, et al., "Glutamine Enhances Selectivity of Chemotherapy Through Changes in Glutathione Metabolism", Annals of Surgery, Vol. 221, No. 4, 420-426, 1995.
		Souba, "Glutamine and Cancer", Annals of Surgery, Vol. 218, No. 6, 715-728, 1993.
		Acree, et al., "A Kinetic Study of the Cyclization of L-Glutamine to 2-Pyrrolidone-5-carboxylic Acid in a Model System", J. Agric. Food Chem., Vol. 23, No. 4, 1975.
		Airaud, et al., "A Research Note: Stability of Glutamine and Pyroglutamic Acid under Model System Conditions: Influence of Physical and Technological Factors", Journal of Food Science, Vol. 52, No. 6, 1987.
		Khan, et al., "The stability of L-glutamine in Total Parenteral Nutrition Solutions", Clinical Nutrition (1991) 10: 193-198
		Gandini, et al., "HPLC Determination of Pyroglutamic Acid as Degradation Product in Parenteral Amino Acid Formulations", Chromatographia, Vol. 36, 1993
		Rieke, et al., "Chronic Intrastriatal L-Pyroglutamate: Neuropathology and Neuron Sparing like Huntington's Disease", Experimental Neurology 104, 147-154 (1989)
		Rieke, et al., "L-Pyroglutamate: An Alternate Neurotoxin for a Rodent Model of Huntington's Disease", Brain Research Bulletin, Vol. 13, pp. 443-456, 1984
		Chanal, et al., "Brain Penetration of Orally Administered Sodium Pyroglutamate", J. Pharm. Pharmacol. 1988, 40: 584-585
		Caccia, et al., "Plasma and Brain Levels of Glutamate and Pyroglutamate After Oral Monosodium Glutamate to Rats", Toxicology Letters, 10 (1982) 169-175
		Ghezzi, et al., "Plasma Pyroglutamic Acid Levels After Oral Administration of Monosodium Glutamate to Human Volunteers", Toxicology Letters, 15 (1983) 123-129
IG		de Mello, et al., "Neurochemical Effects of L-Pyroglutamic Acid", Neurochemical Research, Vol. 20, No. 12, 1995, pp. 1437-1441
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Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
IG	3,787,466	1/22/74	Kagawa, et al			
IG	3,944,681	3/16/76	Friedman, et al			
IG	3,178,342	4/13/65	A. Buzas			

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)
IG	WO 92/09277	6/1/92	Kihlberg, R.			
IG	WO 01/74173 A1	10/11/01	Harris, R.			
IG	EP 0 540 462 A1	6/10/92	Brouns, F.			

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